UNITED STA. , DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/358,153	07/21/99	VAN VENROOIJ	W 30394-1027

005179
PEACOCK MYERS AND ADAMS P C
P O BOX 26927
ALBUQUERQUE NM 87125-6927

HM12/0925

EXAMINER	
MCELWAIN, S	
ART UNIT	**PAPER NUMBER**
1644	17

DATE MAILED: 09/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev. 2/95)
*U.S. GPO: 2000-473-000/44602

1- File Copy

Office Action Summary	Application No. 09/308,150	Applicant(s) Van Venrooroolj et al.
	Examiner DeCloux, Amy	Art Unit 1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jul 6, 2001*

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 3-9, and 15-24* is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 3-9, and 15-24* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

1. Applicant's amendment, mailed 7-2-01 (Paper No. 16), is acknowledged.

2. In view of applicant's amendments, arguments, certified priority document and English translation thereof, mailed 7-2-01 (Paper No. 16), the outstanding objections and art rejections have been withdrawn. Regarding the outstanding 112 2nd paragraph rejections, only part A, as applied to claim 7 only, is maintained. However the 112 first paragraph rejections are maintained. And, in view of the amendments and newly added claims, new grounds of rejection have been applied to the instant claims.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 3, 5-9 and 15-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Applicants traverse said rejection on the grounds that the skilled artisan can recognize the peptides recited in the instant claims because the instant specification discloses said peptides are derived from an antigen recognized by autoimmune antibodies from patients with rheumatoid arthritis, and said peptides all have a modified arginine. However the examiner contends that with the exception of the peptides in Table I, the skilled artisan could not begin to envisage the plethora of antigens, known and unknown, which contain one or more arginine residues modified in one or more ways. Therefore, applicants are essentially describing a huge genus of peptide antigens known and unknown, which contain one or more modified arginine residues and have not narrowed the genus by giving an indication of how to exclude peptide auto-antigens in which arginine residues are not modified. Therefore, though applicant's arguments have been carefully considered, the rejection is maintained.

4. Claims 1, 3, 5-9 and 15-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a peptide from Table 1 , consisting of SEQ ID NO:s 1-9, and a cyclic peptide consisting of SEQ ID NO:10, does not reasonably provide enablement for any peptide from any antigen recognized by autoantibodies from patients with rheumatoid arthritis as recited in the instant claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicant traverse said rejection on the basis that the instant disclosure is more than sufficient to enable one skilled in the art to practice the invention with peptides other than those disclosed and without an undue amount of experimentation. Applicants further contend that there is very specific biochemical information in that said peptides are derived from an antigen recognized by autoimmune antibodies from patients with rheumatoid arthritis, and said peptides all have a modified arginine, with which the examiner agrees. However there is insufficient guidance and direction in the instant specification for predicting which arginines, if any, in any given antigen, known or unknown, will undergo a modification, and which type of arginine modifications will occur, and further, which modifications will then generate or be recognized by the autoantibodies in a patient with rheumatoid arthritis. The examiner agrees with applicant's stating that due to the polyclonal nature of antibodies in sera, a cohort of which may recognize the modified peptide less well due to the arginine modification, as mentioned by applicants, which is consistent with the point illustrated by Abaza et al, (that changing a single amino acid of an antigen even when said antigen is outside ot the epitope binding region, can cause a change in the ability of a monoclonal antibody to bind said antigen) , and is applicable since polyclonal antisera described by applicant is made of individual monoclonal antibodies. It is not clear what applicant meant by the last part of the last sentence on page 11 which reads "while another peptide will better recognize the antigen.".

Therefore, though applicant's arguments have been carefully considered, the rejection is maintained.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

6. Claim 7 is rejected under 35 U.S.C. § 112, second paragraph, as

being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) The phrase "wherein the peptide is derived from a contiguous stretch of amino acid residues encoded by mRNA," as recited in claim 1 upon which claim 7 depends does not appear to apply to claim 7 which recites a synthetic peptide.

Applicants have not addressed this particular claim rejection in said amendment, therefore this rejection is maintained.

NEW GROUNDS OF REJECTION

7. Claims 1, 3-9, 15-16 and newly added claims 17-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims are not supported by the specification or by the claims as originally filed. There is no support in the specification or claims as originally filed for the recitation of a peptide "of about 21 or fewer amino acids" as recited in claim 1 and dependent claims. There is no written description of the claimed invention in the specification or claims as originally filed. Thus the claimed invention constitutes **new matter.** Applicant is invited to point out support for said limitation.

8. Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claim is not supported by the specification or by the claims as originally filed. There is no support in the specification or claims as originally filed for the recitation of a peptide " which modified arginine residue was formed during proteolytic treatment" as recited in claim 9. There is no written description of the claimed invention in the specification or claims as originally filed. Thus the claimed invention constitutes **new matter.** Applicant is invited to point out support for said limitation

9. The following is a quotation of the appropriate paragraphs of *35 U.S.C. § 102* that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 21-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Simon et al J. Clin. Invest. 92:11387-1393, 1993,(IDS), as evidenced by WO/ 99/35167.

Simon et al teach that filaggrin is recognized by auto-antibodies specifically in RA patients (see Abstract and page 1387, column 2, last sentence of second paragraph.). Therefore, the referenced teachings anticipate the claimed references. It is noted that even though the modification of Arginine was not taught, the claimed functional limitations would be inherent properties of the referenced peptides, as evidenced by WO/99/35167. '167 teaches that citrulline containing peptides of human filaggrin reacted with autoantibodies of rheumatoid arthritis (see entire article, especially the Abstract).
Note the open language indicated by the term "having" in line 1 of claim 21. Also note that post filing date references can be used in support of inherent features taught in the primary 102 reference.
Also note The office does not have the facilities and resources to provide the factual evidence needed in order to establish that there is a difference between the Factor V deficient plasma of the prior art and the instant application. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed modifications of filaggrin are different from those taught by the prior art and to establish patentable differences. (See In re Best 562 F.2d 1252 195 USPQ 430 (CCPA) and Ex parte Gray 10 USPQ 2d 1922 (PT) Bd. Pat App. & Int, 1989).

11. Claim 4 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is indefinite in the recitation of "SFQ ID NO 2". Perhaps "SEQ ID NO:2" should be substituted.

12. No claim is allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.**

See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.
Patent Examiner,
Group 1640, Technology Center 1600
September 24, 2001

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644